IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC, Plaintiffs, v. COREVALVE, INC. and MEDTRONIC COREVALVE LLC, Defendants.	)	C.A. No. 08-91 (GMS) REDACTED - PUBLIC VERSION

EDWARDS' OPENING BRIEF IN SUPPORT OF MOTION FOR PERMANENT INJUNCTION, ACCOUNTING AND RELATED RELIEF

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May 28, 2010 - Original Filing Date
June 3, 2010 - Redacted Filing Date

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For years CoreValve, Inc. and Medtronic CoreValve LLC (collectively, "CoreValve") have willfully infringed Edwards Lifesciences LLC and Edwards Lifesciences AG's (collectively, "Edwards") patent. The patented technology involves heart valves delivered via a catheter percutaneously (through the skin), or by a minimally invasive surgical procedure, which obviates the need for traditional open-heart surgery. This revolutionary technology has saved thousands of lives.

An eight-day jury trial was held from March 23 to April 1, 2010. The jury returned a verdict that (1) CoreValve's Generation 3 transcatheter heart valve ("THV"), sold commercially as the ReValving System,[1] literally infringed Claim 1 of Edwards' United States Patent 5,411,552 ("the '552 Patent"); (2) CoreValve's infringement was willful; (3) CoreValve failed to prove that the '552 Patent is not enabled, and therefore invalid; (4) Edwards is entitled to its lost profits of $72,645,555; and (5) Edwards is entitled to reasonable royalties of $1,284,861. [D.I. 313]. Judgment was entered on May 4, 2010.

It took a jury less than four hours to find willful literal infringement and award Edwards all of the lost profits it sought at trial. This case was not a close call. Neither is the question of a permanent injunction, which Edwards now seeks pursuant to 35 U.S.C. § 283.[2]

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1 Medtronic, Inc. acquired CoreValve, Inc. in April 2009. Since Medtronic's acquisition of CoreValve, the ReValving System has also been referred to as the "Medtronic CoreValve System." In this brief, CoreValve's Generation 3 THV devices are referred to collectively as the "ReValving System."

2 In addition to its request for a permanent injunction, and as set forth herein, Edwards seeks certain pre- and post-judgment monetary damages that could not be presented to the jury and thus are not accounted for in the jury's verdict.

SUMMARY OF ARGUMENT

A permanent injunction should be entered against CoreValve precluding further infringement of Claim 1 of Edwards' '552 Patent. Specifically, CoreValve should be barred from making, using, selling, offering for sale, or importing its ReValving System in the United States, and any devices no more than colorably different from the ReValving System. CoreValve should also be barred from supplying or causing to be supplied in or from the United States (1) all or a substantial portion of the components of the ReValving System (or any device not more than colorably different therefrom), where such components are uncombined in whole or in part, in a manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the '552 Patent if such combination occurred within the United States or (2) any component of the ReValving System (or any device not more than colorably different therefrom) especially made or especially adapted for use in the device and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the '552 Patent if such combination occurred within the United States.

CoreValve and Edwards are the only competitors in the THV market. CoreValve received CE approval to sell the ReValving System in Europe in March 2007. (*See* Egan Decl., Ex. 8, PTX 380 (CoreValve's CE Mark certificate for its ReValving System)). Edwards received its CE approval to sell in Europe in September 2007. (*See* Egan Decl., Ex. 4, PTX 2124 (Edwards' CE Mark certificates for its SAPIEN device)). Using that headstart as a beachhead, CoreValve, with ReValving System products manufactured in the United States, secured market

share in Europe and other international locations that otherwise would have been captured by Edwards.[3] After its acquisition of CoreValve in April 2009, Medtronic, one of the world's largest medical device makers, boasted that its "scale and expertise" would "accelerate the use" of CoreValve's ReValving System. (*See, e.g.*, Egan Decl., Ex. 20, PTX 1835 (EDWARDS 239013), Medtronic Press Release "Medtronic Completes Acquisition of CoreValve, Inc." (April 9, 2009)). The continuing, escalating harm to Edwards is irreparable.

Section 283 of the Patent Act permits a district court to grant permanent injunctions to remedy such patent infringement. *See* 35 U.S.C. § 283. To obtain an injunction, a patentee must demonstrate that:

> (A) it has suffered an irreparable injury;
>
> (B) remedies available at law, such as monetary damages, are inadequate to compensate for that injury;
>
> (C) considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and
>
> (D) the public interest would not be disserved by a permanent injunction.

Ebay Inc. v. *MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

In this case, each prong of this four-part injunction analysis weighs heavily in favor of a permanent injunction.

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[3] CoreValve manufactures the ReValving System in Irvine, California. (Trial Tr. (Day 3) at 606:9 to 607:13). There, the pericardial tissue that forms the leaflets and skirt of the device is processed, cut, and sutured to a nitinol stent imported from Germany. (*Id.*; Declaration of Brian P. Egan ("Egan Decl."), Ex. 1, [redacted]

STATEMENT OF FACTS

Edwards is the global leader in the science of heart valves, and is at the forefront of THV product development. Edwards owns the pioneering THV '552 Patent of Drs. Henning R. Andersen, J. Michael Hasenkam, and Lars L. Knudsen.[4] (Trial Tr. (Day 2) at 294:6-21, 467:16 to 469:7). Edwards has commercialized the '552 Patent technology in its SAPIEN product lines and marks its products with the '552 Patent number. (Egan Decl., Ex. 2, PTX 1630; Trial Tr. (Day 2) at 492:21 to 493:12; Trial Tr. (Day 4) at 807:12-19).

The commercial THV market has just two competitors: Edwards and CoreValve. CoreValve's infringing ReValving System competes directly with Edwards' SAPIEN and SAPIEN XT products. (Trial Tr. (Day 3) at 515:1-11, 567:2-4; Trial Tr. (Day 4) at 909:1-3). Both Edwards and CoreValve are approved to commercially sell their respective THV devices in Europe and other countries outside the United States; both are currently seeking FDA regulatory approval for commercial use of their respective products within the United States. (Trial Tr. (Day 2) at 469:8-25, 472:14-24, 473:18-24; Trial Tr. (Day 3) at 524:2-7, 529:18 to 530:8, 566:2-7; Trial Tr. (Day 4) at 950:11 to 951:1).[5] Currently, the transcatheter aortic heart valve market is

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[4] There is no dispute that, unless its term is extended pursuant to 35 U.S.C. § 156, the '552 Patent will expire on May 2, 2012.

[5] *See also* Egan Decl., Ex. 3, Duane Nash et al., "Edwards Lifesciences (EW): Edwards Wins Patent Victory Over Medtronic's THV Device; Increasing Fair Value to $78 from $74," Wedbush Pacgrow Lifesciences Analyst Report, p. 2 (April 5, 2010) (estimating FDA approval for Edwards SAPIEN and SAPIEN XT devices in 2012 and 2013, respectively, and FDA approval for CoreValve's ReValving System in 2014); *id.* at Ex. 4, PTX 2124 (Edwards' CE Mark certificates for its SAPIEN device); *id.* at Ex. 5, Edwards March 2, 2010 Press Release (announcing CE Mark approval of SAPIEN XT device); *id.* at Ex. 6, PTX 2059, 2060 (Edwards' CE Mark certificates for its SAPIEN XT device); *id.* at Ex. 7, [redacted]; *id.* at Ex. 8, PTX 380 (CoreValve's CE Mark certificate for its ReValving System).

split, with each company possessing approximately 50% of the market share. (Trial Tr. (Day 4) at 914:10-24, 992:12-18).

There is no strict hierarchy of preference between the Edwards and CoreValve products, or between the method of delivering a THV (*e.g.*, transfemorally, transapically or via a subclavian approach).[6] (Trial Tr. (Day 2) at 481:11-24; Trial Tr. (Day 3) at 569:22 to 570:3, 572:8-15). It varies by hospital and team of physicians. (Trial Tr. (Day 2) at 481:11-24; Trial Tr. (Day 3) at 569:22 to 570:3, 572:8-15). From Edwards' perspective, it "market[s] the device with one valve [and] two delivery systems, and . . . let[s] the clinicians decide how to best treat any individual patient." (Trial Tr. (Day 2) at 481:11-24). About ninety percent of CoreValve's patient population is treatable with Edwards' current products. (Trial Tr. (Day 4) at 958:17 to 961:12). Edwards expects to be able to treat all of CoreValve's patient population by the fall of 2010, when its 29 mm "large annulus" devices receive CE approval. (Trial Tr. (Day 2) at 488:13-21).[7] In the interim, Edwards' proposed form of injunction contemplates letting

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6 The implantation of transcatheter heart valves is performed through various access points in the body. Transfemoral implantation is typically performed by delivering the THV through the femoral artery; transapical delivery is performed by making a small incision between the ribs of a patient and delivering the THV through the apex of the left ventrical; and subclavian implantation is performed by inserting the THV below the collar bone and delivering the device through the subclavian artery.

7 Currently, Edwards treats patients with aortic annulus sizes up to 25 mm with its 23 mm and 26 mm SAPIEN and SAPIEN XT devices. (Egan Decl., Ex. 2, PTX 1630 at 1 (EDWARDS 242585); *id.* at Ex. 10, [redacted]; *id.* at Ex. 5, Edwards' March 2, 2010 Press Release "Edwards SAPIEN XT Transcatheter Valve and Delivery Systems Receive CE Mark"; Trial Tr. (Day 2) at 469:8-25, 486:20 to 487:2, 488:13-21, 489:14-21). Upon CE approval of its large annulus 29 mm devices (expected fall 2010) Edwards will be able to treat patients with aortic annulus sizes up to 28 mm. (Trial Tr. (Day 2) at 488:13-21, 489:22-24; *see also* Egan Decl., Ex. 4, PTX 2124; *id.* at Ex. 6, PTX 2059, 2060; Trial Tr. (Day 2) at 473:18-24; Trial Tr. (Day 3) at 566:2-7). CoreValve treats patients with aortic annulus sizes up to 27 mm with its 26 mm and 29 mm devices. (Egan Decl., Ex. 10 [redacted]; *id.* at Ex. 11, PTX 23 at 2 (CoreValve ReValving System Instructions for Use)).

CoreValve supply the large annulus portion of the market (about 10%) until Edwards' large annulus product is approved. (*See* Plaintiffs' [Proposed] Order for Permanent Injunction and Related Relief, ¶ 2).

Additional facts pertinent to this motion are set forth below.

ARGUMENT

The facts of this case present a textbook example of when a permanent injunction should issue. CoreValve is a willful infringer and Edwards' sole competitor. CoreValve rushed into the THV market before Edwards. Edwards has lost market share and suffered irreparable harm, while CoreValve enjoyed increased sales and the benefits associated with being the first to market. As set forth below, Medtronic has repeatedly announced publicly that an injunction will not impact its CoreValve business. Moreover, the public interest and public policy favor an injunction in this case.

A. Irreparable Harm is Shown by How CoreValve Caused Edwards to Lose First-Mover Advantage and Market Share

Since it first acquired a license to the '552 Patent as part of its acquisition of Percutaneous Valve Technologies ("PVT"), Edwards has declined to license the '552 Patent for aortic THV applications that are the subject of this lawsuit. Instead, Edwards made every effort to purchase outstanding rights in the '552 Patent, ultimately receiving an assignment of the '552 Patent from the named inventors. (Trial Tr. (Day 2) at 468:14 to 469:7). [redacted]

[redacted]

[redacted]

CoreValve proceeded along a different path. It chose to willfully infringe the '552 Patent, causing Edwards continuing irreparable harm. There is no dispute that Edwards and CoreValve are the only competitors in the aortic THV market, and that CoreValve's ReValving System was the first commercially available THV on the market. (Trial Tr. (Day 3) at 515:1-11, 565:15-24, 567:2-4; Trial Tr. (Day 4) at 909:1-3). Dr. Gregory Leonard, Edwards' damages expert, discussed at length the irreparable harm caused by CoreValve's entry to the THV market ahead of Edwards:

> [T]here is a thing called first-mover advantage which, you know, is commonly talked about in business . . . . [W]hat that is about is that if you manage to be the first one to the market with a new technology, you get to convert a lot of people to your product and get people used to it and build what is called an installed base, which just means people have used it, have liked it, of course, if you have a good product. And then when the second guy comes into the market, it's very hard for them to convert your customers to their product. So what it means is a first mover, the first one to the market tends to maintain a much larger share of the market than, you know, and is impervious, to some extent, to the competition when it comes in later. So if Edwards had two years here on the market [before CoreValve entered], they would have been able to train a whole bunch of doctors and centers. And that training creates a first mover advantage because once doctors train, they tend to use the product that they've been trained on, and it would make it tough for CoreValve to come in second.

(Trial Tr. (Day 4) at 954:17 to 955:13; *see also* Trial Tr. (Day 3) at 515:4-23, 565:15 to 567:4; *i4i Ltd. P'ship* v. *Microsoft Corp.*, 598 F.3d 831, 861 (Fed. Cir. 2010) ("Past harm to a patentee's

market share, revenues, and brand recognition is relevant for determining whether the patentee 'has suffered an irreparable injury.'")).

Courts typically award permanent injunctions where the plaintiff practices its invention and the infringing defendant is plaintiff's only competition. *See Trueposition Inc.* v. *Andrew Corp.*, 568 F. Supp. 2d 500, 531 (D. Del. 2008).[8] In *Trueposition*, the plaintiff and defendant were the only two competitors making use of the patented technology, and the defendant, beating plaintiff to market, made the first commercial sale of the patented technology in the international market. *Id.* Under those facts, Judge Robinson held that:

> Defendant's infringement . . . has necessarily affected its goodwill and its reputation as the first company to provide [the patented technology] outside the U.S. As plaintiff and defendant are the only suppliers in a two-supplier market, defendant's infringement has necessarily affected plaintiff's market position. On this record, plaintiff has established irreparable harm.

Id. at 532 (citing *Muniauction*, 502 F. Supp. 2d at 482; *Novozymes A/S* v. *Genecor Intern., Inc.*, 474 F. Supp. 2d 592, 612-13 (D. Del. 2007)).

Here, too, Edwards and CoreValve are the only two competitors commercially selling the patented technology, and CoreValve's ReValving System entered the market first. As in *Trueposition*, the harm caused by CoreValve's willful infringement is irreparable. Not only has Edwards lost a substantial share of the market because of CoreValve's willful infringement,

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[8] *See also Muniauction, Inc.* v. *Thomson Corp.*, 502 F. Supp. 2d 477, 482 (W.D. Pa. 2007) (awarding permanent injunction where "[p]laintiff and defendants are direct competitors in a two-supplier market"); *Johns Hopkins Univ.* v. *Datascope Corp.*, 513 F. Supp. 2d 578, 586 (D. Md. 2007) (granting permanent injunction where infringing product was plaintiffs' "only competition" and "thus, its sale reduce[d] the [p]laintiffs' market share"); *Martek Biosciences Corp.* v. *Nutrinova Inc.*, 520 F. Supp. 2d 537, 558-59 (D. Del. 2007) (granting permanent injunction where plaintiff was a direct competitor "likely to lose market share that it may not be able to recapture," as plaintiff's patented technology was its primary revenue source, and defendant was plaintiff's only competitor and was "targeting [plaintiff's] customers in that industry")).

Edwards lost the opportunity to establish relationships and train medical centers that it otherwise could have had CoreValve not been on the market. [redacted] Trial Tr. (Day 3) at 514:24 to 516:16, 517:7 to 519:18 (discussing PTX 1664), 520:10 to 521:1 [redacted], 522:7-22; Trial Tr. (Day 4) at 964:12 to 965:17, 976:15 to 977:7). Moreover, Edwards' reputation as a global leader in the science of heart valves has been compromised by CoreValve's early unauthorized entry to the market and continued willful infringement. (*See, e.g.*, Egan Decl., Ex. 17, PTX 381 (CoreValve May 16, 2007 Press Release referring to the ReValving System as "patented" and "novel" and highlighting that "CoreValve's *ReValving* System is the first cath lab-based procedure for percutaneous aortic valve replacement to receive European regulatory clearance")).

The wound to Edwards is widening. In a CNBC interview just one week after the April 1 jury verdict, William Hawkins, Medtronic's CEO, further exacerbated the harm to Edwards' reputation as innovator. Mr. Hawkins held up a sample of CoreValve's ReValving System on national television, touting it as an example of "innovation that [Medtronic] . . . [is] bringing forth . . . [that] will reduce costs and improve [patient] outcomes." (*See* Egan Decl., Ex. 18, CD of April 8, 2010 CNBC Interview of Bill Hawkins, *available at* http://www.cnbc.com/id/15840232?video=1463650005&play=1).

Even the jury award in this case cannot remedy the harms suffered by Edwards. Absent an injunction, Edwards will be deprived of its right to exclude its sole competitor from infringing the '552 Patent. *See* 35 U.S.C. § 154(a)(1). "In view of that right, infringement may cause a patentee irreparable harm not remediable by a reasonable royalty." *Acumed LLC* v. *Stryker Corp.*, 551 F.3d 1323, 1328 (Fed. Cir. 2008). This is particularly true where, as here, the patent-in-suit is close to expiration. *See H.H. Robertson, Co.* v. *United Steel Deck, Inc.*, 820

F.2d 384, 391 (Fed. Cir. 1987) (affirming district court's grant of injunction where the "equities weigh[ed] heavily against the wrongdoer" because the patent did "not have many more years to run"); *Honeywell Int'l, Inc.* v. *Universal Avionics Sys. Corp.*, 397 F. Supp. 2d 537, 543 (D. Del. 2006) ("[there is a] need for injunctive relief to avoid irreparable harm when limited time is left on the life of a patent").

Edwards has been and will continue to be irreparably harmed absent an injunction.

B. Monetary Relief is Inadequate to Compensate Edwards

Legal remedies are not adequate to compensate Edwards for CoreValve's willful infringement of the '552 Patent. Where, as here, the infringing party is the patentee's only competition in the market, courts have repeatedly held that monetary damages are insufficient compensation for infringement because the loss in market share, business opportunities, and reputation is incalculable. *See Martek*, 520 F. Supp. 2d at 558-59 (holding that plaintiff will continue to suffer irreparable harm that cannot be compensated monetarily, including the loss in market share, if defendant, plaintiff's *only* competitor, is not enjoined); *Novozymes*, 474 F. Supp. 2d at 612-13 (holding that "[l]egal remedies are not adequate to compensate Novozymes for the infringement of its patent" because "the statutory right to exclude represents a benefit that, under these circumstances, cannot be equated by an award of cash. These are head-to-head competitors, and Novozymes has a right, granted by Congress, not to assist its rival with the use of proprietary technology."). As the Court observed in *Trueposition*: "This conclusion is bolstered by the jury's finding that defendant's infringement of the [ ] patent was willful." 568 F. Supp. 2d at 532.

Edwards cannot quantify the harm it will incur if CoreValve continues to use the '552 Patent technology for the remainder of the '552 Patent's life. Just as in *Trueposition*,

> [T]he value of defendant's continued infringement . . . is unknown. Defendant has taken from plaintiff not only this important business, but the recognition of being a technology innovator and the first global supplier of the patented technology, and an unquantifiable amount of business opportunities flowing therefrom. Such harms are not compensable in damages.

Trueposition, 568 F. Supp. 2d at 532. If Edwards "cannot prevent its only competitor's continued infringement of its patent, the patent is of little value." *Muniauction*, 502 F. Supp. 2d at 482.

Monetary relief simply is inadequate to compensate Edwards.

C. Balance of Hardships Favors Edwards

Edwards will suffer great hardship if a permanent injunction does not issue to stop CoreValve's willful infringement of the '552 Patent.[9] Allowing one of the world's largest medical device makers – Medtronic – to continue to manufacture an infringing device within the United States for international distribution would suffocate Edwards in the marketplace. Medtronic's 41,000 employees and $50 billion market capitalization dwarf Edwards' 6,400 employees and $5.7 billion market capitalization. (*See* Egan Decl., Ex. 3, Duane Nash et al., "Edwards Lifesciences (EW): Edwards Wins Patent Victory Over Medtronic's THV Device; Increasing Fair Value to $78 from $74," Wedbush Pacgrow Lifesciences Analyst Report, p. 4, Table 2 (April 5, 2010); *see also id.* at Ex. 19, excerpts from Edwards Lifesciences' February 26, 2010 Form 10-K Report and Medtronic, Inc.'s June 23, 2009 Form 10-K Report (detailing

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[9] "[T]he balance considered is only between a plaintiff and a defendant, and thus the effect on customers and patients . . . is irrelevant under this prong of the injunction test." *Acumed*, 551 F.3d at 1330 (citing *Ebay*, 547 U.S. at 391).

employment figures)). Medtronic can reach into its deep pockets, flood the market with its infringing product, and further dilute Edwards' market share. (*See, e.g.*, Egan Decl., Ex. 20, PTX 1835 (EDWARDS 239013), Medtronic Press Release "Medtronic Completes Acquisition of CoreValve, Inc." (April 9, 2009) (Medtronic boasting that its "scale and expertise" would "accelerate the use" of CoreValve's ReValving System); *id.* at Ex. 25, Bhalla et al., "Medtronic CoreValve HQ Visit," Citi Analyst Report, p. 2 (Dec. 10, 2009) ("[CoreValve] [m]anagement indicated that the integration of CoreValve was ahead of its plans and manufacturing output has tripled since the acquisition due to a number of improvements at the Irvine, CA facility." (emphasis supplied))). This would perpetuate the injustice of CoreValve's first-mover advantage, and further reward CoreValve's willfully infringing behavior. Without a permanent injunction, Edwards will suffer continued loss in its sales, customers, resources and reputation.

No such hardship will befall CoreValve if the injunction is granted. Medtronic, Inc., CoreValve's parent company, announced on the day of the jury verdict that, "[i]n the event of a U.S. injunction, Medtronic has manufacturing capabilities for CoreValve products outside the United States to ensure continued supply worldwide." (*See* Egan Decl., Ex. 21, Medtronic April 1, 2010 News Release). As the press has reported: "[Medtronic has] suggested directly that they will have manufacturing outside the U.S. up and running in not much more than 30 days [from April 8, 2010] and certainly less than 60 [*i.e.*, by June 7, 2010]." (*See* Egan Decl., Ex. 9, Bob Hopkins *et al.*, "MDT: Bullish Management Meetings," Bank of America Merrill Lynch Analyst Report (April 8, 2010); *see also id.* at Ex. 22, Bob Hopkins *et al.*, "MDT Infringes EW Patent," Bank of America Merrill Lynch Analyst Report (April 5, 2010) ("[Medtronic] is in the process of moving manufacturing for CoreValve's European business to Mexico. . . . The process of moving manufacturing to Mexico began in December of 2009 and

[Medtronic] is implying they can begin to ship from Mexico within a month or two . . . ."); *id.* at Ex. 25, Bhalla et al., "Medtronic CoreValve HQ Visit," Citi Analyst Report, p. 2 (Dec. 10, 2009) ("a second manufacturing facility is expected in Tijuana, Mexico")). As such, Medtronic has admitted it will experience no hardships upon the issuance of an injunction.[10] *See Novozymes*, 474 F. Supp. at 613 ("The balance of hardships tips in favor of Novozymes. While Novozymes would suffer irreparable harm from future infringement, Defendants, who have apparently pulled the infringing product from the market, will not be harmed by a permanent injunction.").

The balance of hardships heavily favors Edwards.

D. A Permanent Injunction Will Not Disserve the Public Interest

In this case, a permanent injunction will not disserve the public interest. Protection and enforcement of patent rights in the field of medical devices is particularly important. *See, e.g.*, *Becton Dickinson & Co.* v. *Tyco Healthcare Group LP*, Civ. A. No. 02-1694, 2008 WL 4745882, *4 (D. Del. Oct. 29, 2008). Patents are critical to a company's ability to raise capital, fund costly medical device research and development, guide a medical device through FDA and foreign regulatory approval, scale production and bring a product to market.

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[10] Even if CoreValve were to receive FDA approval for commercial sale of its device in the United States prior to the expiration of the '552 Patent, which CoreValve itself does not expect, a permanent injunction against CoreValve would result in minimal hardship. The CoreValve ReValving System is estimated to amount to only about 1% of Medtronic's revenues through 2012. (Egan Decl., Ex. 3, Duane Nash et al., "Edwards Lifesciences (EW): Edwards Wins Patent Victory Over Medtronic's THV Device; Increasing Fair Value to $78 from $74," Wedbush Pacgrow Lifesciences Analyst Report (April 5, 2010); *see also* Egan Decl., Ex. 23, Debra Sherman, "ANALYSIS- Medtronic Ups Stake in Heart Valves with ATS Deal," Reuters (Apr. 29, 2010) *available at* http://www.reuters.com/article/idUSTRE63S4S220100429 ("Scott Ward, president of Medtronic's cardiovascular business, . . . said . . . the patents Edwards holds will probably have expired by the time the CoreValve product is launched in the United States . . . . We don't anticipate launching (the CoreValve product) in the U.S. until 2014")).

Edwards' '552 Patent is no exception. Larry Wood, Edwards' corporate representative at trial and head of Edwards' THV division, testified that:

> If someone could wait until you did all the heavy lifting and did all the design work and then they could just copy your design and bring it to market, they would come to market without any of that initial investment and could cut your price or do other things. If that happened, then you couldn't afford to make these investments in medical innovation and you couldn't run a business that way.

((Trial Tr. (Day 2) at 454:2 to 455:7 (further noting that patents are critical to Edwards' business model, and that Edwards has invested in excess of $400 million bringing its patented SAPIEN technology to market); *see also* Trial Tr. (Day 3) at 533:6-9 (Edwards has spent over $100 million seeking FDA regulatory approval for its SAPIEN device)). Edwards invested hundreds of millions of dollars optimizing and bringing to market its groundbreaking THV technology, and the public interest in protecting Edwards' patent rights in this field is paramount. The ability to enforce medical device patents must be strong -- if Edwards and other medical device companies cannot rely on the patent system as protection for their investments, the process of bringing innovative medical devices technology to market will fail. *See Honeywell*, 397 F. Supp. 2d at 547 ("'[W]ithout the right to obtain an injunction, the right to exclude granted to the patentee would have only a fraction of the value it was intended to have, and would no longer be as great an incentive to engage in the toils of scientific and technological research.'" (citation omitted)).

Even with lifesaving technology, district courts have weighed in favor of permanent injunctions:

> While the public interest is unquestionably advanced through the marketing of potentially lifesaving devices such as Medtronic's, Congress has determined it better for the nation in the long run to afford the inventors of novel, useful and non-obvious products short-term exclusivity on such products rather than to permit free

> competition in the goods. Congress has not seen fit to differentiate between what might be referred to as lifesaving devices and those of a more trivial or less important nature.
>
> The public interest is served by granting injunctions to effectuate patent rights.

Eli Lilly & Co. v. *Medtronic Inc.*, 7 U.S.P.Q.2d 1439, 1445 (E.D. Pa. 1988) (issuing permanent injunction against Medtronic), *rev'd on other grounds*, 872 F.2d 402 (Fed. Cir. 1989).

Medtronic initially stated that it will oppose any effort by Edwards to seek an injunction against the CoreValve product in the United States, including because of the public interest. (See Egan Decl. Ex. 21, Medtronic April 1, 2010 News Release). This position is directly at odds with Medtronic's subsequent statements to the press and analysts that moving its manufacturing operations off shore is a non-event. *See supra* Sec. IV(C), pp. 11-12. Today, CoreValve is only able to implant its device outside of the U.S., and Medtronic has made clear that it has sufficient manufacturing capabilities in Mexico to facilitate demand abroad.

Currently, Edwards can treat all CoreValve patients outside the U.S. except those with aortic annulus sizes larger than 25 mm. Edwards expects to receive CE Mark approval for its 29 mm SAPIEN device later this year, which will allow Edwards to treat this remaining patient population. "[T]he touchstone of the public interest factor is whether an injunction, both in scope and effect, strikes a workable balance between protecting the patentee's rights and protecting the public from the injunction's adverse effects." *i4i Ltd. P'Ship*, 598 F.3d at 863. As a result, Edwards acknowledges that the injunction should be tailored to allow CoreValve to manufacture in the United States a limited number of ReValving Systems to treat patients with aortic annulus sizes larger than 25 mm until Edwards receives CE Mark approval for its 29 mm

SAPIEN device. A proposal for such a modified injunction is set forth in Paragraph 2 of the Proposed Order submitted herewith.[11,12]

A permanent injunction will also not harm U.S. patients. Edwards expects to have full approval by FDA of its products prior to CoreValve, and will be able to treat any patient CoreValve could treat.

Thus, the public interest will not be disserved by entry of Edwards' proposed form of permanent injunction in this case.

ACCOUNTING AND RELATED RELIEF

The damages calculations presented at trial by Edwards' damages expert, Dr. Gregory K. Leonard, and adopted in relevant part by the jury, were based on sales through March 15, 2010. Devices made, used, sold, offered for sale, imported or supplied in or from the United States post March 15, 2010 were not addressed at all in the damages calculations or verdict. As such, in addition to the entry of a permanent injunction, Edwards requests the Court

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11 [redacted] Edwards is entitled to a royalty on any such infringing units.

12 Edwards also recognizes that certain uses of CoreValve's ReValving System within the United States during the FDA regulatory approval process may fall within the Safe Harbor exemption under 35 U.S.C. § 271(e)(1). This exemption is not to be abused, however, and Edwards' proposed permanent injunction carefully limits CoreValve's uses within the United States to only those uses required by the FDA prior to CoreValve's receipt of PMA approval. [redacted]

order an accounting of the number of CoreValve Revalving System devices made, used, sold, offered for sale, imported or supplied in or from the United States and corresponding revenue from March 16, 2010 through the date of its Order on this Motion. Once that accounting is made, Edwards will be able to calculate and present to the Court its monetary damages not covered by the April 1 jury verdict, plus pre-judgment and post-judgment interest. (*See* Plaintiffs' [Proposed] Order for Permanent Injunction and Related Relief, ¶¶ 4, 5).

CONCLUSION

For the foregoing reasons, Edwards respectfully requests that the Court issue a permanent injunction and order an accounting and related relief, as set forth in the accompanying Proposed Order, enjoining CoreValve's continued willful infringement of the '552 Patent, and ordering an accounting of CoreValve's sales so that pre- and post-judgment damages and interest not accounted for in the jury's verdict may be calculated.[13]

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[13] Should the Court decline to order a permanent injunction against CoreValve, Edwards reserves the right to move the Court to order a compulsory license for an ongoing royalty for all infringing sales of CoreValve's ReValving System through the expiration of the '552 Patent. *See Paice LLC* v. *Toyota Motor Corp.*, 504 F.3d 1293, 1314 (Fed. Cir. 2007) ("awarding an ongoing royalty for patent infringement in lieu of an injunction may be appropriate . . . where 'necessary' to effectuate a remedy").

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May 28, 2010 - Original Filing Date
3565633
June 3, 2010 - Redacted Filing Date

CERTIFICATE OF SERVICE

I hereby certify that on May 28, 2010 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

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I further certify that I caused copies of the foregoing document to be served on May 28, 2010 upon the following in the manner indicated:

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